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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	**PAPER NUMBER**
1753	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,649	FREEMAN ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) *1-4,7-10,14-23 and 29-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,9,10,15-18,20-23 and 29-34* is/are rejected.

7)☒ Claim(s) *8,14 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Amendment

1. Applicant's amendment of July 11, 2003 does not render the application allowable.

Response to Arguments

2. Applicant's arguments filed July 11, 2003 have been fully considered but they are not persuasive. Applicant argues that Shine WO'600, Friese '604, Knoll '401, Watanabe '362, and Toyama '778 "relate solely to a macroelecrode system. Thus, none of the references relate to the present invention at all." The examiner respectfully disagrees.

Shine WO'600 teaches that the conductive layer may be made of foil 25 to 100 μm thick or a deposited coating "from a few atoms to 25 μm thick" (pg. 7, ll. 1-10). Additionally, the reference teaches "the aperture preferably has an internal diameter in the range of 40 to 160 μm" (pg. 7, ll. 28-29).

Friese '604 teaches electrodes having a thickness of 8 to 15 μm (col. 3, ln. 64 – col. 4, ln. 4). Additionally, the reference teaches an aperture diameter of 0.25 mm (col. 4, ll. 65-68).

Knoll '401 does not specifically mention that the electrodes are microscale; however, this is obvious as the electrodes are formed by sputtering or vapor deposition (col. 7, ll. 1-10) and the dielectric layer is 0.1 to 1 mm thick (col. 5, ll. 50-54). Additionally, the reference teaches an aperture diameter of between 10^{-4} to 10^{-1} mm (col. 6, ll. 5-8).

Watanabe '362 teaches electrodes about 10 μm thick (col. 3, ll. 60-63). Additionally, the reference teaches an aperture diameter of about 1 mm (col. 3, ll. 50-55).

Applicant also states that the Fukuda et al. reference does not disclose a common well bottom for collinear wells. A common well bottom (14a) for collinear wells is shown in Figures 5 and 6(C).

Thus, several of Applicant's claims are rejected as being unpatentable over the prior art cited above.

Status of Rejections Applied in the Office action of December 31, 2003

3. All previous rejections are withdrawn.

Claim Objections

4. Claims 29, and 32-34 are objected to because of the following informalities:

a) Claim 29, line 9: -- the -- should be inserted between "at" and "least";

b) Claim 32, line 9: -- the -- should be inserted between "at" and "least";

c) Claim 33, line 5: "contract"; and

d) Claim 34, line 9: -- the -- should be inserted between "at" and "least".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claims 22 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 22 and 34 require the specialized layer to be "provided with means to apply physical or chemical gradients or potential thereto." This means-plus-function limitation fails to satisfy 35 U.S.C. 112, first paragraph, because it encompasses means based on a large number of possible phenomena, such as gravity, electrical fields, osmotic pressure, temperature differential, and pressure, and the disclosure does not explicitly or implicitly set forth the structure, materials, or acts corresponding to the means-plus-function limitation. See page 2100-219 of the MPEP, Rev. 1 Feb. 2003. Applicant is limited to the structure, material, or acts described in the specification and equivalents that correspond to the means-plus-function limitation; however, no such structure, material, or acts have been set forth.

6. Claims 22 and 30-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claims 30 and 31 depend from cancelled claim 24;

b) Claim 32 requires that the conducting layer be treated with an organic conducting layer. Does the microelectrode system actually contain an organic conducting layer or is this limitation a product-by-process limitation that dos not actually result in a structural modification to the metallic conducting layer?

c) Claim 33: it is not clear whether the conducing layer is actually in the microelecrode system as the contact means need only be able to contact an unspecified conducting layer; and

d) Claims 22 and 34 require the specialized layer to be "provided with means to apply physical or chemical gradients or potential thereto." This means-plus-function limitation fails to satisfy 35 U.S.C. 112, second paragraph because "there is no disclosure of structure, material or acts for performing the recited function." See page 2100-217 of the MPEP, Rev. 1 Feb. 2003.

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-3 and 16-18 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Shine et al. (WO 9724600 A1).

Addressing Claim 1, the Shine et al. reference teaches a microelectrode system comprising a laminated structure (the abstract; Figures 3 and 6; and page 7, ll. 1-4) having

- at least one conducting layer made of foil 25 to 100 μm thick or a deposited coating "from a few atoms to 25 μm thick" (pg. 7, ll. 1-10) capable of acting as an electrode (**3** or **14** in Figure 3 or **203** or **214** in Figure 6);
- at least one dielectric layer (**2** in Figure 3 or the unlabeled insulating layer between electrodes **203** and **214** in Figure 6);
- an aperture formed in the laminated structure with a diameter of 0.25 mm, wherein the aperture is a through hole which extends through the laminated structure and is open at both ends (Figures 3 and 6); and
- contact means for allowing electrical contact with at least one conducing layer (**10** or **17** in Figure 3 or **210** or **217** in Figure 6).

Addressing Claim 2, an aperture defining a non-uniform internal wall may be seen in Figures 3 and 6.

Addressing Claim 3, an aperture defining a substantially tubular internal wall in the laminate structure is shown in Figure 1.

Addressing Claim 16, a gold conducting layer is disclosed on page 10, lines 16-19.

Addressing Claim 17, a dielectric layer as claimed is disclosed on page 10, lines 8-15 and Figures 3 and 6.

Addressing Claim 18, syringes are disclosed in Figure 7.

9. Claims 1-3, 18, and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Friese et al. (US 5,314,604).

Addressing Claim 1, the Friese et al. reference teaches a microelectrode system comprising a laminated structure (the abstract; Figures 1A and 2A; and col. 4, ll. 52-54) having

- at least one conducting layer 8 to 15 μm thick (col. 3, ln. 64 – col. 4, ln. 4) capable of acting as an electrode (**6**, **8**, or **8'** in Figures 1A or 2A);
- at least one dielectric layer (col. 4, ll. 10-14);

- an aperture formed in the laminated structure with a diameter of 0.25 mm (col. 4,
- ll. 65-68), wherein the aperture is a through hole which extends through the laminated structure and is open at both ends (Figure 1A); and
- contact means for allowing electrical contact with at least one conducing layer (**6'**, **9'**, or **11'** in Figures 1A, 1B, 2A, or 2B).

Addressing Claim 2, an aperture defining a non-uniform internal wall may be seen in Figures 1A and 2A.

Addressing Claim 3, an aperture defining a substantially tubular internal wall in the laminate structure is shown in Figures 1 and 2.

Addressing Claim 18, electrode pumps are disclosed in col. 3, ll. 22-25.

Addressing Claim 21, solid electrolyte layers are disclosed in col. 3, ll. 14-20.

Claim Rejections - 35 USC § 103

10. Claims 1, 2, 4, 7, 10, 15, 16, 21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knoll (US 5,393,401).

Addressing Claim 1, the Knoll reference teaches a microelectrode system comprising a laminated structure (the abstract; Figures 4 and 7-10) having

- at least one conducting layer capable of acting as an electrode (**16**, **32**, or **33** in Figures 4 and 7-10);
- at least one dielectric layer (**15** in Figures 4 and 7-10);
- an aperture formed in the laminated structure with a diameter of 10^{-4} to 10^{-1} mm (col. 6, ll. 5-8), wherein the aperture is a through hole which extends through the laminated structure and is open at both ends (Figures 1-12); and
- contact means for allowing electrical contact with at least one conducing layer ((not shown in the figures but implied by, for example, col. 7, ll. 10-13, which teaches an electrical connection to an integrated circuit).

The Knoll reference does not mention that the conducting layer is in the range of 1 to 10 microns; however, this is arguably within the scope of this reference because col. 7, ll. 1-10; col. 5, ll. 51-54; and Figures 4 and 7-10 teach forming the conducting layer by sputtering or vapor depositing the conducting layer onto a wafer that is less than 0.1 mm thick and is several times thicker than the conducting layer. In any event, it would have been obvious to one with

ordinary skill in the art at the time the invention was made to scale the invention down if smaller sample volumes are expected.

Addressing Claim 2, an aperture defining a non-uniform internal wall may be seen in Figures 4 and 7-10.

Addressing Claim 4, a plurality of apertures is implied by Figure 4, which shows a schematic for an array of sensors.

Addressing Claim 7, electrode **16** or **32** is functionalized by the ionophore in membrane **7.**

Addressing Claim 10, a plastic base is shown Figure 12.

Addressing Claim 15, a silver/silver chloride reference electrode is taught in col. 8, ll. 13-19 and col. 8, ll. 37-44.

Addressing Claim 16, a gold conducting layer is disclosed in col. 7, ll. 1-10.

Addressing Claims 21 and 23, in the aperture, level with a dielectric layer, gel, solid electrolyte, and membrane containing ionophore may be present (col. 8, ll. 20-30).

11. Claims 1, 2, 7, 9, 10, 15-17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al. (US 4,647,362).

Addressing Claim 1, the Watanabe et al. reference teaches a microelectrode system comprising a laminated structure (the abstract; Figure 1; and col. 3, ll. 60-65) having

- at least one conducting layer 10 μm thick (col. 3, ll. 60-63) capable of acting as an electrode (any metal layer **2** shown Figure 1);
- at least one dielectric layer (any insulating layer **1** shown in Figure 1);
- an aperture formed in the laminated structure with a diameter of 1 mm (col. 3, ll. 50-55), wherein the aperture is a through hole which extends through the laminated structure and is open at both ends (Figure 1); and
- contact means for allowing electrical contact with at least one conducing layer (any lead **8** shown in Figure 1).

The aperture in the Watanabe et al. reference is 1 mm; however, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have the aperture diameter in the range of 0.5 to 500 microns to better accommodate smaller sample volumes. That is, it is obvious to scale the invention down if smaller sample volumes are expected.

Addressing Claim 2, an aperture defining a uniform internal wall in the laminate structure is shown in Figure 1.

Addressing Claim 7, electrode **2** (shown in magnified view as **24** in Figure 1) is fictionalized by ion sensitive layer **3.**

Addressing Claim 9, as seen in Figure 1 consecutive conducting layers are separated by dielectric layers.

Addressing Claim 10, either endmost dielectric layer can be construed as a based. In the Watanabe et al. reference the dielectric layer can be made from materials such as Bakelite, epoxy resins, polyvinylchloride resins, ceramics (col. 3, ll. 55-59).

Addressing Claim 15, a silver/silver chloride reference electrode is taught in col. 4, ll. 2-14.

Addressing Claim 16, a gold conducting layer is disclosed in col. 3, ll. 65-67.

Addressing Claim 17, a dielectric layer as claimed is disclosed in col. 3, ll. 50-59 and Figure 1.

Addressing Claim 20, alternating conducting and dielectric layers are disclosed in Figure 1.

12. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over JPO computer translation of Fukuda (JP 06324014 A).

The Fukuda reference teaches a microelectrode system comprising a laminated structure (the abstract; Drawings 2 and 4-6; paragraph [0022] of the *Detailed Description*; and paragraph [0029] of the *Detailed Description*), having

- at least one conducting layer 0.3 microns thick capable of acting as an electrode (elements **16** and **18** and paragraph [0029] in *Example*),

- at least one dielectric layer (**14** or **20**),

- at least one pair of apertures formed in the laminated structure into at least one pair of substantially collinear wells having a common bottom (Drawings 4-6, note common well bottom 14a), and

- contact means for allowing electrical contact with at least one conducing layer (for example **18b** and **16b** in Drawing 3(A); also see paragraph [0019] of the *Detailed Description*).

The Fukuda reference only mentions an embodiment apparently smaller than claimed by Applicant (paragraph [0029] in *Example*). However, it would have been obvious to one with ordinary skill in the art at the time of the invention to scale the microelectrode system to best accommodate the expected sample volumes.

Allowable Subject Matter

13. Claims 8, 14, and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Claim 34 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. 112, second paragraph, set forth in this Office action.

15. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 8 requires "at least one dielectric layer to be made from a rubbery material having a solid-state matrix capable of swelling in the presence of a liquid or gas." In the Shine et al. reference the dielectric is the same material used in printed circuit boards (page 4, lines 35-37). In the Friese et al. the dielectric layer is made form Al_2O_3 (col. 4, ll. 10-14). In the Knoll reference the dielectric layer is made from silicon (col. 5, ll. 50-53). In the Watanabe et al. reference the dielectric layer can be made from materials such as Bakelite, epoxy resins, polyvinylchloride resins, ceramics (col. 3, ll. 55-59);

b) Claim 14 requires at least one conducing layer to be metallic and treated with an organic conducting layer. None of the conducting layers in the Shine et al., the Friese et

al., the Knoll, or the Watanabe et al. references have been treated with an organic conducting layer;

c) Claims 19 and 33 require that means for assisting mass transport be a piezoelectric vibrator or ultrasonic probe. The Shine et al., the Friese et al., the Knoll, and the Watanabe et al. references do not disclose such an assisting mass transport means. In these references the means for assisting mass transport is gravity or pressurized flow;

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguerola
Alex Noguerola
9/26/2003
Primary Examiner
TC 1700